# PATENT SPECIFICATION

DRAWINGS ATTACHED

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## COMPLETE SPECIFICATION

## Sutures

We, NATIONAL RESEARCH DEVELOPMENT CORPORATION, a British Corporation established by Statute, of Kingsgate House, 66 to 74 Victoria Street, London, S.W.1, formerly of 1 Tilney Street, London, W.1, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to the suturing of body tissues, that is to say to sutures for holding severed tissues together, at least until a natural bond forms to reunite them permanently. Once this bond is formed the suture used is sometimes removed. In particular the invention applies to the suturing of tendons, especially those that are enclosed within a synovial sheath, e.g. tendons at the wrist and in the fingers, toes and foot.

It is customary to suture such tendons with fine thread (e.g. linen, silk, nylon or stainless steel wire). The two ends of the proximal and distal parts of the severed tendon are cut cleanly so as to give fresh surfaces which may reunite and to remove ragged strands, foreign body particles and adhesions (scars). The ends are then held together by a continuous length of fine thread inserted into both parts of the severed tendon by a needle. The thread must engage with at least one of the severed parts in such a way that traction may be exercised upon that part by pulling the thread, whereby to press the two cleanly cut ends in contact with one another until they reunite naturally. The necessary passage of the thread through the tendon for purposes of anchorage damages it, and when the thread is drawn taut the part of the tendon where the thread is anchored is distorted and constricted. This impedes the repair of the tendon; extra adhesions or scars are formed and the ability of the tendon to glide smoothly within its sheath or surrounding tissues is impaired. Moreover, the few blood vessels in the tendon will be constricted or even occluded, and the tendon may be forced to rely greatly upon the surrounding tissues to support the healing process.

According to the present invention, a suture for effecting and maintaining contact between tissues comprises a thread having attached to it or formed upon it, over a limited part of its length, a plurality of barbs the tails of which point away from the leading end of the thread, at which there may be a needle. There may also be a needle at the other (or trailing) end of the thread. The invention also includes a thread having two distinct sections of its length barbed. These two lengths are close to each other, and the tails of the barbs of each length point towards the small intervening length of unbarbed thread in the middle. According to another of its features the invention comprises a suture for effecting and maintaining contact between tissues, in the form of a thread which has first been drawn and on which there have then been attached or formed over a limited part of its length, a plurality of barbs the tails of which point away from one end of the thread.

The invention includes applications of the suture. The needle is inserted into tissue and passed out through the other end or the surface of it until the barbed length of the thread is totally within the tissue. Traction on the trailing end of the thread will result in the fine barbs anchoring within the interstices of the tissue and resisting removal. The trailing end of the thread may be attached to another part of the tissue, or to another

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tissue, by a knot or attachment to a button on a suitable surface—e.g. the skin. If the trailing end of the thread has a barbed length it also may obtain anchorage in a like manner to the leading end by insertion into another part of the same tissue, or into a second tissue. The two tissues, or tissue ends, may then be drawn together until they abut. A suture applied in the first of these ways may later, if desired, be removed. That applied in the second way will remain permanently *in situ* even after natural union between the abutting parts is established.

Sutures according to the invention and methods of using them, will now be described, by way of example, with reference to the accompanying diagrammatic drawings, in which:—

Figure 1 is a cross section through a tendon with a sheath (as found in the hand, for example);

Figures 2 and 3 are longitudinal sections through tendons with sheaths, sutured by customary methods;

Figures 4 and 5 are longitudinal sections through tendons with sheath, sutured in recently described methods;

Figure 6 is an elevation of one suture according to the present invention;

Figure 7 is a longitudinal section through a tendon sutured by the suture of Figure 6;

Figure 8 is a longitudinal section through another tendon sutured by the suture of Figure 6;

Figure 9 is an elevation of another suture according to the present invention;

Figure 10 is a longitudinal section through a tendon sutured by the suture of Figure 9;

Figure 11 is an elevation, on a larger scale, of part of an actual suture as shown in Figure 6, and

Figure 12 is a diagrammatic cross section taken through part of a suture as shown in Figure 6 during its manufacture.

The unit of tendon structure is the tendon fascicle 1 comprising a closely packed bunch of stout collagen fibres 2 bound together by a network of very fine collagen fibres, the endotenon 3. A large number of fascicles are held together and covered by a smooth layer of fine fibres, the peritenon 4, and the whole constitutes what will henceforth be called a tendon 5. To ensure smooth gliding motion the tendons of some muscles are invested in certain specific sites with a tendon sheath. Such sites include the wrist and fingers. The exact form of the sheath is complex but it may be simply represented by an outer tube of smooth tissue 7 separated from the tendon by a space 6 containing a little free tissue fluid.

A fine flexible thread 8 of silk, linen, nylon or wire has been used for the suture shown in Figure 2. The extremities of the two severed parts 9 and 10 of the tendon 5 have been cut cleanly leaving faces 11 and 12. Part 9 is the proximal end, i.e. the muscle end of the tendon; part 10 is the distal end which is linked to a bone. In order to bring the cleanly cut faces 11 and 12 together the thread 8 is inserted by a needle into the face 11; it passes in a short diagonal path out of the tendon at a point 13, to re-enter again close to this point and pass across the tendon diagonally to the opposite side, to emerge at another such point 13 and then re-enter again, thus zig-zagging down a short length of the tendon. When sufficient passes to and fro have been made, the thread is zig-zagged back to the face 11. The needle is now inserted into the face 12 and the same procedure followed until the thread re-appears at the interface between 11 and 12. The thread is then drawn taut, the needle removed, and the two loose ends are knotted at 14 at the interface. A natural union should be formed at the interface in three to four weeks, and the suture will then no longer be required to take any strain or tension. It remains permanently buried within the tendon; the exposed length of thread will be covered over by new peritenon as part of the natural repair process. When the tendon is repaired it may also be necessary to repair the sheath 7 by sewing the severed ends together with fine thread 14a.

It will readily be seen that this type of suture involves extensive passage of thread through the tendon, thus endangering the blood vessels therein, and that the inevitable uneveness of the tendon wall at the several points 13 where the thread emerges and re-enters may impair the ability of the mended tendon to glide smoothly within the mended sheath.

Figure 3 shows a similar but more complex method of suturing which may permit removal of the thread once natural union is established. Thread 8 with a needle at both ends is used. One needle is inserted into the face 11 of the proximal part 9, and zig-zagged up and down it as before, emerging again at the face 11. Both needles are now inserted through the face 12 into the distal part 10, and pass along parallel but not coincident paths through the tendon wall, the space 6, the sheath 7, the subcutaneous tissues 18 and the skin 17. They are anchored here by a button 16, under sufficient tension to close the gap between 11 and 12. Before this tension is applied, however, a thread 15 is passed under the thread 8 at the most proximal and superficial vertex of the zig-zag path of the thread through the part 9, i.e. at 13a. Both free ends of thread 15 are threaded to a needle by which they are passed out through space 6, sheath 7, tissues 18, and

skin 17, both ends of the thread travelling along a common path. The thread 15 is left slack and its two ends are located at the skin by another button 16. When natural union between 11 and 12 is thought to have taken place, the buttons 16 are removed and by pulling on the two free ends of thread 15 it may be possible to remove both this thread and thread 8 from the body. However, the thread 8 sometimes breaks in this process, and even if it is removed cleanly damage to the blood vessels and the smoothness of the tendon wall may occur.

Figures 4 and 5 show tendons sutured in two recently described methods, similar to each other. Here wire thread 20 has been inserted by needle through the wall of the proximal part 9 of the tendon 5, then down the core of that part and out through the face 11 until a small flat plate or "gig" 21 (Figure 4) or double barb 22 (Figure 5) engages in the outer surface of part 9. The needle then carries the thread 20 into the face 12 of the distal part 10 of the tendon, down its core, out through its wall and so to the skin 17. The thread is pulled distally to hold faces 11 and 12 together, and the button 16 is then attached. Another button locates the slack trailing end of the thread 20 against the skin also. When natural union has occurred, the slack trailing end is pulled to remove the thread 20 from the body. At their insertion, both gig 21 and double barb 22 may cause extensive damage to as yet undamaged parts of tendon and sheath. At their removal, they will damage the subcutaneous tissues 18 and skin 17 as well. Furthermore, they engage on the surface of the tendon and in fact are partly buried in tendon substance while repair is taking place. They must therefore jeopardise the smoothness of the co-operating surfaces of the repaired tendon and sheath.

The suture according to this invention shown in Figure 6 comprises a nylon monofilament 23 (referred to now as a thread) bonded at each end to eyeless needles 24, 25. The middle of the thread has been shaped and then cut so as to present four rows of fine barbs 26, the tails 27 of which all point away from the leading needle 24.

When the suture of Figure 6 is used to form the suture of Figure 7, leading needle 24 must be inserted into the face 11, down the core of the proximal part 9 and out through the surface of this part at 28. It then passes out through the skin and is attached loosely to a button 16. The trailing needle 25 is now inserted through the face 12 and down the core of the distal part 10 of the tendon, out through the wall of this part at 29, and so out through the skin when a button 16 is attached after the thread has been pulled taut to bring the faces 11, 12 into contact. The needles are then removed. When natural union has taken place, the leading end is pulled and the thread removed from the body.

With this kind of suture, it will be seen that the length of thread within the tendon is kept to a minimum, and the barbs are fine and may be pliable and so may damage the tendon interior less than the considerable lengths of thread inserted in the zig-zag paths of some known methods. Further, the barbs damage the surface of the tendon and the sheath at only one point, and that only on removal—not during insertion.

Figure 8 shows another application of the suture of Figure 6, in which the suture remains *in situ* even after natural union has taken place. The leading end of the thread is cut off flush at 28. At the point 30 where the trailing end emerges from the tendon wall there is no sheath, since this has been reflected back on to the part 10 at 31. The trailing end passes through the skin at 32, where it is located by a button 16 after traction has been applied to bring the faces 11, 12 together. When natural union has taken place, the button is removed and the trailing end cut off flush with the skin. Although the suture remains *in situ*, it does not impair the gliding function of the major part of the tendon within its sheath, since at the point where the suture emerges from the tendon wall there is no sheath. This application of a suture as shown in Figure 6 is suitable not only for the repair of severed tendons but for tendon attachment, transfer, and possibly grafting.

A second suture according to the invention, shown in Figure 9, comprises a nylon monofilament (thread) 33 having four rows of barbs 34 formed on two short lengths of it 35 and 36, one on either side of the mid-point and separated by an unbarbed length 37. The tails of all the barbs all point towards the mid-point. At the ends of the monofilament 33 are fixed fine eyeless needles 38, 39. Figure 10 shows an application of the suture of Figure 9. Needle 38 is inserted into face 11 of the proximal part 9, and passes down the core thereof to emerge through the tendon wall at 40. The needle is not passed through the skin but is pulled until the whole of the barbed length 35 is within the part 9. Thread 33 is then cut off flush with the tendon surface at 40. The other needle 39 is now inserted similarly through the face 12 of the distal part 10, down the core and out of that part at 41. The faces 11, 12 are now butted together, and the loose end cut off at 41.

Figure 11 is a plan view based on a photograph of a suture actually made and of the type shown in Figure 6.

The suture is made from drawn monofilament nylon of circular cross section 23 (shown in a dashed line in Figure 12) which

is rolled to produce a monofilament of cruciform cross section as shown in Figure 12. The ribs 43 of the cross are so cut by either a simple angled cut or a 'V' shaped cut 42 to produce a series of barbs 44, which are distorted or bent outwards to make the slender barbs 44 more prominent. The suture is finally twisted in its longitudinal axis to produce a long spiral.

The dimensions of the suture vary and are dependent upon the size and site of the tendon to be repaired.

The following is a range of sizes of particular sutures according to the invention, and is given by way of example only.

Circular monofilament Nylon. Diameter (i.e. distance D in Figure 12) 0.018—0.025 inches.

Cruciform monofilament Nylon as shown in Figure 12. Diameter (i.e. distance d in Figure 12) 0.020—0.030 inches.

Rib height (i.e. distance h in Figure 12 approximately one third of the diameter) 0.007—0.010 inches.

Barb height (i.e. distance h' in Figure 12. Greater than rib height if distorted) 0.007—0.020 Inches.

Barb section length. (i.e. section 26 in Figures 6, 7 and 8; section 35 and 36 in Figures 9 and 10) 10—20 barbs. 0.327—0.787 inches (0.75—2.0 cm).

Unbarbed section, ends between needle and barbed section. (i.e. section 23 in Figure 6; section 33 in Figure 9) 1.0—2.0 inches.

Unbarbed section, middle between barbed section (i.e. section 37 in Figure 9) 0.062—0.25 inches.

Needles 24, 25, 38, 39. Fine eyeless, round bodied and cutting, straight and slightly curved.

Although the invention has been described with principal reference to sutures made from nylon monofilament, other plastics, possibly in multifil or other forms, may be suitable. The sutures may also be moulded. The use of metals (viz. silver, stainless steel, tantalum) is also contemplated. A more efficient barbed suture may possibly be made by attaching barbs to a thread rather than forming them integrally on it; the barbs may be of a material different from that of the thread (viz. plastic barbs on wire suture). A wire thread could have greater tensile strength than a plastic one, and plastic barbs could be more resilient than wire, therefore causing less damage during insertion, and possibly during removal also.

The invention has been described with principal reference to the suturing of tendons with and without a sheath but may also be applicable to the repair of other tissues, e.g. skin, fascia, cartilage, muscle and subcutaneous fat tissue. Those sutures according to the present invention which have already been used for the repair of cadaver tendons have appeared to exhibit at least the following advantages; little distortion or constriction of the joint faces (11, 12); minimal damage of the tendon wall; no knots required (a knot reduces the tensile strength of a thread by up to 50%) and ease of insertion.

WHAT WE CLAIM IS:—

1. A suture for effecting and maintaining contact between tissues comprising a thread having a first end and a second end and having attached to it or formed upon it, over a limited part of its length, a plurality of barbs the tails of which point away from the first end of the thread.

2. A suture according to claim 1 in which the thread has a further limited part of its length barbed, the two parts being separated from each other by an intervening third part which is unbarbed, and the tails of the barbs of each of the barbed parts pointing towards the intervening unbarbed third part.

3. A suture according to claim 1 or claim 2 in which the or each barbed part has the barbs arranged in a plurality of rows each row running longitudinally of the thread.

4. A suture according to claim 1 or claim 2 in which the or each barbed part has the barbs arranged in a plurality of rows each of which forms a helix around the longitudinal axis of the thread.

5. A suture according to claim 3 or claim 4 in which there are four rows of barbs.

6. A suture according to any preceding claim in which a needle is attached to the first end of the thread.

7. A suture according to claim 6 in which another needle is attached to the second end of the thread.

8. A suture according to any preceding claim in which the barbs are pliable.

9. A suture for effecting and maintaining contact between tissues, comprising a thread which has first been drawn and on which there have then been attached or formed over a limited part of its length, a plurality of barbs, the tails of which point away from one end of the thread.

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1 SHEET This drawing is a reproduction of the Original on a reduced scale